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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,967	02/04/2000	Theodore G. Clark	235.00170101	8124

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EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	16

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/497,967	Clark et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 3, 2002* .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-7, 10-15, and 17-37* is/are pending in the application.

4a) Of the above, claim(s) *1, 2, 12, 13, 15, 22, and 24-35* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *3-7, 10, 11, 14, 17-21, 23, 36, and 37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's amendment filed December 3, 2002 (Paper Number 15) has been received and entered. Claims 8, 9, and 16 have been canceled and new claims 36-37 have been added. Consequently, claims 1-7, 10-15 and 17-37 are pending in the instant application. It is further noted that claims 1-2, 12-13, 15, 22, and 24-35 have been withdrawn from further consideration as being drawn to a non-elected invention. Consequently, claims 3-7, 10-11, 14, 17-21, and 36-37 are under consideration, to their full extent, in the present application.

All grounds of rejection in the Office Action mailed January 2, 2002 are withdrawn.

The following new grounds of rejection are applied to the claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claims 3-5, 10-11, 14, 17, 19, and 36 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 3-5, 10-11, 14, 17, 19, and 36 are directed to a sequence of nucleotides which have the same characteristics as polynucleotides found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated polynucleotide..."

Claim Rejections - 35 USC § 112

2. Claims 6, 21 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a T. thermophila host cell transformed with a heterologous DNA construct, does not reasonably provide enablement for a transgenic cell. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's specification demonstrates the transformation of heterologous DNA into T. thermophila. However, this does not provide enablement for all transgenic host cells. Transgenic host cells can include human cell lines. Applicant's have provided no guidance or working examples of any transformed cell line other than T. thermophila.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See page 1116). Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Thus, Applicant's have not provided sufficient guidance to enable one skilled in the art to make and use any transgenic cell in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance, the changes which can be made is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and

improperly, extensive and undue. See Ex parte Forman, 230 USPQ 546 (Bd. Pat. App. & Int. 1986).

3. Claims 3-4, 6-7, 10-11, 14, 17-21, 23 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 3-4, 6-7, 10-11, 14, 17-21 and 37 recite a nucleic acid molecule encoding an antigenic protein or peptide fragment.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 7 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 7 which would adequately describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed

genus. Given that the function of the fragments is not set forth, the written description of the instant application is supportive of only an antigenic peptide consisting of fragments of SEQ ID NO: 7, since additional amino acids on the N-terminus or C-terminus will have a profound impact on the activity of the protein.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

4. Claims 3-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of "at least about." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. "At least" one thousand degrees in claim means minimum temperature of one thousand degrees "About" in claim allows some tolerance. National Research Development Corp v. Great Lakes Carbon Corp. (DC

Del) 188 USPQ 327. Consequently, the term at least about confers two separate contradictory limitations.

5. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "substantially complementary." One of skill in the art would be unable to determine the metes and bounds of the claimed invention. For instance what is the line of demarcation between substantially complementary and not substantially complementary? (e.g., 99%, 90%, 75%, etc). Without a clear definition as to what is or is not substantially complementary, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

It is noted that Applicant's have asserted that the term "substantially complementary" is defined in detail at page 17, ine 24 to page 18, line 6. However, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are directed to any DNA that hybridizes to the DNA sequence under conditions of "standard hybridization." Possibilities for hybridization are determined by the stringency of the procedure. Stringency, determined by the physical and chemical conditions, establishes the degree of hybridization. Without a clear definition of the physical and chemical conditions of the "standard hybridization" as well as that of the wash step, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 4, 6-7, 10-11, 14, 17, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Clark et al.

The claims are directed to a nucleic acid molecule comprising a polynucleotide fragment having a nucleotide sequence that encodes at least one terminal portion of an I-antigen

polypeptide having amino acid sequence SEQ ID NO: 7, said terminal portion comprising at least about 10 amino acids.

Clark et al (PNAS USA, Vol. 89, No. 14, pp 6363-6367, July 15, 1992) disclose of the recombinant expression of the Ichthyophthirius multifilis I-antigen. (See abstract).

In view that Clark et al disclose of a nucleic acid molecule that encodes at least one terminal portion of an I-antigen polypeptide having amino acid sequence SEQ ID NO: 7, and that this portion comprises at least 10 consecutive amino acids of SEQ ID NO: 7, the disclosure of Clark et al is deemed to anticipate the claimed invention. (See attached Sequence Search).

It is noted that Applicant's have asserted that Clark et al does not have terminal portions of 10 or more amino acids in common. However, Dorlands Medical Dictionary, 27th Edition defines "terminal" as an extremity. In view that the 10 consecutive amino acids disclosed by Clark et al are located towards the extremity, (i.e., not in the middle) the disclosure of Clark et al is deemed to anticipate the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached

on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

April 7, 2003